

REMARKS

The Examiner is thanked for her assistance during a telephone conference of July 5, 2006.

Claims 1-101 are pending in this application. Claims 97-101 are added. Support for the added claims can be found throughout the specification and in the claims as originally filed. Particular support for "small molecule" can be found, for example, on page 5, line 3. Particular support for "MW167" can be found in Example 1, beginning on page 96. No new matter is added.

The Office Action requires an election under 35 U.S.C. § 121 from among the following:

- I. Claims 1-69, drawn to a method for modulating an immune response by administering a modulator of Notch intracellular protease activity, classified in class 435, subclass 7.21;
- II. Claims 70 and 71, drawn to a modulator and a composition comprising the modulator, classified in class 514, subclass 885;
- III. Claims 72-74 and 78-79, drawn to a method for producing lymphocytes, classified in class 435, subclass 2;
- IV. Claims 75-77 and 80-81, drawn to a method for treating a subject having a disease of abnormal lymphocyte activity by administering cells produced by Group III, classified in class 424, subclass 93.1;
- V. Claim 83, drawn to a method of vaccinating a subject against a tumor by administering a tumor antigen, classified in class 435, subclass 130.1;
- VI. Claims 84-88, drawn to a method for identifying modulators of Notch intracellular domain protease activity, classified in class 435, subclass 7.21;
- VII. Claims 89-96, drawn to a composition comprising a modulator of Notch intracellular domain protease activity and an antigen determinant, classified in class 424, subclass 9.1.

Group I, claims 1-69, is elected with traverse for further prosecution in this application. Applicants note that added claims 97-101 are also directed to a method for modulating an immune response by administering a modulator (more specifically, an inhibitor) of Notch intracellular protease activity. Therefore, claims 97-101 should also be examined in group I. Applicants reserve the right to file divisional applications to non-elected subject matter.

The Office Action further required several elections of species upon election of group I:

- i) a single agonist selected from A) polypeptides/fragments/peptides, B) nucleic acids, C) compounds or D) antibodies, recited in claims 4 and 8;
- ii) a single condition of administration from A) ex vivo or B) in vivo, recited in claims 36, 27, 65 and 66;
- iii) a single effect of modulator selected from A) up-regulates/enhancer or B) down-regulates/inhibitor, recited in claims 9, 11, 13, 14, 22, 23, 25, 26, 28, 29, 31, 32, 34, 40, 47, 48, 51, 52, 58-61 and 69;
- iv) a single T-cell selected from A) effector, B) helper, C) cytotoxic or D) regulatory recited, in claims 20-35;
- v) a single polypeptide selected from A) Notch ligands, B) Noggin, C) Chordin, D) Follistatin, E) Xnr3, F) FGF, G) Toll-like receptor, H) cytokine, I) BMP, J) BMP receptor or K) activin, recited in claims 13 and 14;
- vi) a single cytokine selected from A) IL-10, B) IL-5, C) IL-4, D) IL-2, E) TNF- α , F) IFN- γ or G) IL-13, recited in claims 46-61;

Applicants elect, with traverse:

- i) C) compounds, recited in claims 4 and 8;
- ii) B) in vivo administration, recited in claims 36, 37, 65, and 66;
- iii) B) down-regulates/inhibitor, recited in claims 9, 11, 13, 14, 22, 23, 25, 26, 28, 28, 31, 32, 32, 35, 40, 47, 48, 51, 52, 58, 59, 60, 61, 69 and 97-101;
- iv) D) regulatory, recited in claims 20-35;
- v) small molecules, recited in claim 100;
- vi) A) IL-10, recited in claims 46-61.

Claim 1 is generic. It is Applicants' understanding that, upon the allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all of the limitations of an allowed generic claim, as provided by 37 C.F.R. 1.141. It is also understood that the Examiner can broaden the search to include other species, *e.g.*, upon determining that a species is allowable, or when there is a relationship among the species and/or number of species is not too great.

As a traverse, it is noted that the MPEP lists two criteria for a proper restriction

requirement. First, the inventions must be independent or distinct. (MPEP § 803) Second, searching the additional inventions must constitute an undue burden on the Examiner if restriction is not required. *Id.* The MPEP directs the Examiner to search and examine an entire application “[i]f the search and examination of an entire application can be made without serious burden, ...even though it includes claims to distinct or independent inventions.” *Id.*

It is submitted that the criteria listed in MPEP § 803 have not been met in this case, as Applicants believe that an undue burden would not be placed on the Examiner. Indeed, any search for the methods of group I and at least the methods of groups III, V and VI would certainly be co-extensive, as all are classified in the same class, and group VI is classified in the same subclass as group I.

Enforcing the present restriction requirement would result in inefficiencies and unnecessary expenditures by both the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, a shortened patent term may result in any divisional applications filed). Restriction has not been shown to be proper, especially since the requisite showing of serious burden has not been made in the Office Action and there are relationships between the claimed combinations. Indeed, the search and examination of groups I, III, V and VI is likely to be co-extensive and, in any event, would involve such interrelated art that the search and examination of at least groups I, III, V and VI can be made without undue burden on the Examiner. All of the preceding, therefore, weighs against restriction.

In view of the above, reconsideration and withdrawal of the Requirement for Restriction are requested, and an early action on the merits earnestly solicited.

Respectfully submitted,

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